



# General

#### Title

End stage renal disease (ESRD): percentage of patient months for all pediatric (< 18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was  $spKt/V \ge 1.2$ .

# Source(s)

Centers for Medicare & Medicaid Services (CMS). Measure information form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 5 p.

Centers for Medicare & Medicaid Services (CMS). Measure justification form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 20 p.

# Measure Domain

# Primary Measure Domain

Clinical Quality Measures: Outcome

# Secondary Measure Domain

Does not apply to this measure

# **Brief Abstract**

# Description

This measure is used to assess the percentage patient months for all pediatric (less than 18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurements of the month using the urea kinetic modeling [UKM] or Daugirdas II formula) was a spKt/V greater than or equal to 1.2.

#### Rationale

In considering target spKt/V, the pediatric population should receive at least a spKt/V of 1.2, which is the

minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of clinical performance measures (CPM) data further support this cut-off since adolescents with spK/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2 to 1.4.

#### Evidence for Rationale

Centers for Medicare & Medicaid Services (CMS). Measure justification form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 20 p.

## Primary Health Components

End stage renal disease (ERSD); hemodialysis (HD); spKt/V dose; children; adolescents

### **Denominator Description**

To be included in the denominator for particular month, a patient must be on hemodialysis for the entire month, must be less than 18 years old at the beginning of the month, must have had end-stage renal disease (ESRD) for greater than 90 days at the beginning of the month, must be on thrice weekly incenter hemodialysis during the month, and must be assigned to that facility for the entire month. See the related "Denominator Inclusions/Exclusions" field.

### **Numerator Description**

Number of patient months from the denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the urea kinetic modeling [UKM] or Daugirdas II formula) was a spKt/V greater than or equal to 1.2 (see the related "Numerator Inclusions/Exclusions" field)

# Evidence Supporting the Measure

# Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

# Additional Information Supporting Need for the Measure

High Priority

In the adult population, outcome studies have shown an association between dose of hemodialysis and clinical outcomes (Lowrie et al., 1981; Owen et al., 1993). No equivalent large scale clinical trials have been conducted in the pediatric population but smaller scale observational studies support the association between delivered dialysis dose and patient outcomes (Gorman et al., 2006) including the potential for improved growth with intensive hemodialysis regimens (Fischbach et al., 2006). In considering target spKt/V, the pediatric population should receive at least an spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of clinical performance measure (CPM) data further support this cut-off since

adolescents with spKt/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2 to 1.4 (Gorman et al., 2006). A higher target Kt/V may be necessary in the pediatric population given the increased dietary needs to ensure growth, but there is insufficient evidence to support increasing target Kt/V based on hospitalization rates and mortality. Furthermore, a proportion of pediatric patients receive a dialysis dose below the target adult spKt/V suggesting that even with this target, there is room for improvement in quality of care.

### Evidence for Additional Information Supporting Need for the Measure

Centers for Medicare & Medicaid Services (CMS). Measure justification form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 20 p.

Fischbach M, Terzic J, Menouer S, Dheu C, Soskin S, Helmstetter A, Burger MC. Intensified and daily hemodialysis in children might improve statural growth. Pediatr Nephrol. 2006 Nov;21(11):1746-52. [26 references] PubMed

Gorman G, Furth S, Hwang W, Parekh R, Astor B, Fivush B, Frankenfield D, Neu A. Clinical outcomes and dialysis adequacy in adolescent hemodialysis patients. Am J Kidney Dis. 2006 Feb;47(2):285-93. PubMed

Lowrie EG, Laird NM, Parker TF, Sargent JA. Effect of the hemodialysis prescription of patient morbidity: report from the National Cooperative Dialysis Study. N Engl J Med. 1981 Nov 12;305(20):1176-81.

Owen WF, Lew NL, Liu Y, Lowrie EG, Lazarus JM. The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. N Engl J Med. 1993 Sep 30;329(14):1001-6. [25 references] PubMed

# **Extent of Measure Testing**

Reliability Testing

#### Method of Reliability Testing

The developer used January 2013 – December 2013 CROWNWeb and Medicare claims data to calculate the inter-unit reliability (IUR) for the overall 12 months to assess the reliability of this measure. The National Quality Forum (NQF)-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The IUR measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based IUR was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. The developer notes that the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. Since this measure is not normally distributed, the IUR value should be interpreted with some caution.

#### Statistical Results from Reliability Testing

For reliability the developer calculated the monthly and annual IUR across the 12 reporting months. As explained above, the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. IUR=0.807 with the confidence interval being (0.623, 0.929). This suggests that 81% of variation in the measure is attributed to between facility variation.

#### Interpretation

The IUR suggest this measure is moderately reliable. However, since the distribution of performance scores is skewed, the IUR value should be interpreted with some caution.

Validity Testing

Method of Validity Testing

Assessment based on face validity by the 2010 hemodialysis (HD) pediatric technical expert panel (TEP).

Statistical Results from Validity Testing

This measure is being maintained on the basis of face validity.

Use of small solute clearance (urea reduction ratio and more recently Kt/V) as a dialysis quality measure was initially developed and approved by the clinical TEP in 2010 on pediatric dialysis adequacy, which agreed that this quality measure domain is important in the assessment of the quality of care for pediatric dialysis patients. Achieving target Kt/V was finalized for the End-stage Renal Disease (ESRD) Quality Incentive Program QIP beginning with program year (PY) 2015, and has been reported on Dialysis Facility Compare (DFC) since January 2013.

In July 2015, the Centers for Medicare and Medicaid Services (CMS) and the University of Michigan Kidney and Epidemiology Cost Center (UM-KECC) revised this measure in response to concerns from the NQF Steering Committee regarding the appropriateness of single pool Kt/V for measuring Kt/V in patients who are dialyzing 3 or 4 times per week. Members of the committee argued that single pool Kt/V is not appropriate for assessing patients on different dialysis frequencies, i.e., 3 or 4 times. Standard Kt/V would be more appropriate for assessing different dialysis frequencies, such as 3 or 4 times per week.

The 2010 TEP that recommended this measure originally specified that the measure include patients on dialysis 3 or 4 times per week. This was based in part on analyses presented at that 2010 TEP meeting showing that 4 times per week hemodialysis was observed in approximately 5.6% of pediatric patient weeks, and nearly 90% of pediatric patient weeks reflected either 3 or 4 times per week hemodialysis (based on 2007 Medicare claims data). Given that this was not an insignificant proportion of patients, as the TEP concluded that these patients should all be included in this measure. UM-KECC recently updated this analysis using 2014 Medicare claims data. This showed that 4 times per week hemodialysis is now observed in 8.06% of patient weeks and approximately 92% of pediatric patient weeks reflected either 3 or 4 times per week hemodialysis. Results were generally similar using 2014 CROWNWeb data. About 7% of pediatric patient weeks were 4 times per week hemodialysis, and 94% of pediatric patient weeks were 3 or 4 times per week.

In response to the NQF Steering Committee concerns of including patients on 3 or 4 times per week dialysis, UM-KECC contacted the members of the 2010 TEP and asked them to consider a revision to limit the measure to pediatric patients on three times a week dialysis. This revision would make this pediatric hemodialysis adequacy measure consistent with the corresponding adult measure (#0249). A majority of the TEP members supported this revision. To date, 5 of the 2010 TEP members (including the TEP chair) voted to revise the measure and limit it to pediatric patients on 3 times per week dialysis (the 2 remaining TEP members have not yet responded to the request for their feedback on this proposed change). The revised measure retains face validity based on the results of this vote.

Here is the specific decision provided by the TEP Chair on behalf of the TEP:

Specifically, the Pediatric CMS-TEP (2010) members who participated in the Pediatric Hemodialysis Adequacy Technical Expert Panel acknowledged that the measure developed in 2010 pertaining to the use of spKt/V stipulated that the measure should include patients on 3 and 4 times per week dialysis. However, they also appreciate the concern of the NQF steering committee charged with reviewing the measure for maintenance of endorsement that "the UKM or Daugirdas formulas are designed for a fixed number of dialysis treatments a week, not 3 or 4." In addition, they recognize that there are no data justifying the inclusion of children who receive more than 3 sessions of dialysis per week in this measure. As a result, the TEP members are in favor of revising the specifications to limit the measure to pediatric patients receiving dialysis 3 times per week. They believe that this would be consistent with the adult measure, which specifies that the measure is for adult hemodialysis patients dialyzing 3 times per week (patients dialyzing less than 3 or greater than 3 times per week are excluded).

Refer to the original measure documentation for additional information.

# Evidence for Extent of Measure Testing

Centers for Medicare & Medicaid Services (CMS). Measure justification form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 20 p.

# State of Use of the Measure

#### State of Use

Current routine use

#### **Current Use**

not defined yet

# Application of the Measure in its Current Use

## Measurement Setting

Ambulatory Procedure/Imaging Center

**Hospital Outpatient** 

Managed Care Plans

# Professionals Involved in Delivery of Health Services

not defined yet

# Least Aggregated Level of Services Delivery Addressed

Single Health Care Delivery or Public Health Organizations

# Statement of Acceptable Minimum Sample Size

Does not apply to this measure

# Target Population Age

Age less than 18 years

# **Target Population Gender**

Either male or female

# National Strategy for Quality Improvement in Health Care

# National Quality Strategy Aim

Better Care

# National Quality Strategy Priority

Prevention and Treatment of Leading Causes of Mortality

# Institute of Medicine (IOM) National Health Care Quality Report Categories

#### IOM Care Need

Living with Illness

#### **IOM Domain**

Effectiveness

# Data Collection for the Measure

# Case Finding Period

The measurement period

# Denominator Sampling Frame

Patients associated with provider

# Denominator (Index) Event or Characteristic

Clinical Condition

Patient/Individual (Consumer) Characteristic

Therapeutic Intervention

#### **Denominator Time Window**

not defined yet

# Denominator Inclusions/Exclusions

#### Inclusions

To be included in the denominator for particular month, a patient must be on hemodialysis for the entire month, must be less than 18 years old at the beginning of the month, must have had end-stage renal disease (ESRD) for greater than 90 days at the beginning of the month, must be on thrice weekly incenter hemodialysis during the month, and must be assigned to that facility for the entire month.

Note:

Patients with missing Kt/V values are not excluded from the measure. Therefore, patients for whom a Kt/V value is missing for the month are still included in the denominator. This is designed to ensure that facilities will still be evaluated for the measure. Refer to the original measure documentation for additional denominator details and calculation algorithm/measure logic.

#### Exclusions

Exclusions that are implicit in the denominator definition include:

Patients on home hemodialysis

Patients on peritoneal dialysis

Patients on ESRD less than 91 days

Patients not on thrice weekly dialysis

Patients not assigned to the facility for the entire month

# Exclusions/Exceptions

not defined yet

### Numerator Inclusions/Exclusions

#### Inclusions

Number of patient months from the denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the urea kinetic modeling [UKM] or Daugirdas II formula) was a spKt/V greater than or equal to 1.2

Note:

Months with spKt/V greater than or equal to 1.2 are counted in the numerator. Eligible spKt/V values are those greater than or equal to 1.2 during the reporting month. The last spKt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month.

Missing, expired, and not performed are not counted as achieving the minimum spKt/V threshold.

Exclusions

Unspecified

# Numerator Search Strategy

Fixed time period or point in time

#### Data Source

Administrative clinical data

Registry data

# Type of Health State

Physiologic Health State (Intermediate Outcome)

# Instruments Used and/or Associated with the Measure

Unspecified

# Computation of the Measure

# Measure Specifies Disaggregation

Does not apply to this measure

# Scoring

Rate/Proportion

### Interpretation of Score

Desired value is a higher score

# Allowance for Patient or Population Factors

not defined yet

# Standard of Comparison

not defined yet

# **Identifying Information**

# **Original Title**

Minimum spKt/V for pediatric hemodialysis patients.

#### Measure Collection Name

End Stage Renal Disease (ESRD) Quality Measures

#### Submitter

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

# Developer

Centers for Medicare & Medicaid Services - Federal Government Agency [U.S.]

# Funding Source(s)

# Composition of the Group that Developed the Measure

The University of Michigan Kidney and Epidemiology Cost Center (UM-KECC), develops, maintains, and updates the End Stage Renal Disease (ESRD) Quality Measures for the Centers for Medicare and Medicaid Services (CMS), under the Quality Measure Development and Maintenance contract with CMS. In addition, UM-KECC works with CMS's Measures Management System (MMS) in the development, evaluation, and reporting of the current ESRD Quality Measures.

### Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

#### Endorser

National Quality Forum - None

### **NQF Number**

not defined yet

#### Date of Endorsement

2015 Oct 2

# Measure Initiative(s)

Dialysis Facility Compare (DFC)

# Adaptation

This measure was not adapted from another source.

# Date of Most Current Version in NQMC

2015 Sep

#### Measure Maintenance

Annually

# Date of Next Anticipated Revision

Unspecified

#### Measure Status

Please note: This measure has been updated. The National Quality Measures Clearinghouse is working to update this summary.

### Measure Availability

Source available from the Dialysis Data Web site	
For more information, refer to the Dialysis Data Web site	or contact Casey
Parrotte at the Kidney Epidemiology and Cost Center, The University of Mich	igan, 1415 Washington
Heights, Suite 3645 SPHI, Ann Arbor, MI 48109-2029; Phone: 734-763-6611;	Fax: 734-763-4004; Email:
parrotte@med.umich.edu.	

# **NQMC Status**

This NQMC summary was completed by ECRI Institute on December 5, 2014. The information was verified by the measure developer on February 6, 2015.

This NQMC summary was updated by ECRI Institute on July 14, 2016.

# Copyright Statement

No copyright restrictions apply.

# Production

# Source(s)

Centers for Medicare & Medicaid Services (CMS). Measure information form: minimum spKt/V for pediatric hemodialysis patients. Baltimore (MD): Centers for Medicare & Medicaid Services (CMS); 2015 Sep 25. 5 p.

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# Disclaimer

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